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Remarks

Applicant, herein, has canceled claims 2, 12, 13 and 22-24, and has amended claims 11, 20, 21 and 32. Twenty-six (26) claims remain pending in the application: claims 1, 3-11, 14-21 and 25-32. Applicant respectfully requests reconsideration of the pending claims, in view of the claim amendments above and comments below.

Claim Rejections - 35 USC § 112

In paragraphs 1 and 2 of the Office Action mailed September 12, 2003, claims 2, 12, 13, 22 and 24 were rejected under 35 U.S.C. 112, second paragraph, as indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Applicant has herein canceled a number of claims, including claims 2, 12, 13, 22 and 24, rendering this rejection moot.

Claim Rejections - 35 USC § 103

In paragraphs 3, 4 and 5 of the Office Action, claims 1-6, 8-17, 19-23, 27, 30, 31 and 32 were rejected under 35 U.S.C. 103(a) as unpatentable (obvious) over Tanagho et al (4703755) in view of Schulman et al (5193540). Specifically, in paragraph 5, the Examiner states (emphasis added):

Tanagho et al discloses a method and device for controlling bladder function. The device includes multiple electrode stimulators. The electrodes are implanted near the S2, S3, and S4 nerves and provide inhibitory stimulation pulses in the range of 5 to 40 Hz to control incontinence and 15 to 50 Hz to begin evacuation of the bladder.

Applicant respectfully traverses this rejection, as the stimulation provided by Tanagho et al is *not* inhibitory stimulation, as shown below. In contrast, inhibitory stimulation is taught in the subject application and claimed in all of the pending claims (after entry of the amendments herein).

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For instance, applicant's claims 1 and 31 specify that *inhibitory* stimulation pulses delivered to *parasympathetic nerves* treat urgency, frequency, urinary incontinence, and/or fecal incontinence. Applicant's amended claims 20 and 32 specify that *inhibitory* stimulation pulses delivered to *sympathetic nerves* treat urinary and/or fecal retention. Applicant's amended claim 11 specifies that *inhibitory* stimulation pulses delivered to *parasympathetic nerves* treat urgency, frequency, urinary incontinence, and/or fecal incontinence, while excitatory stimulation of those same nerves treats urinary and/or fecal retention.

Tanagho did not recognize that *different types* of stimulation (i.e., excitatory stimulation to activate a nerve; inhibitory stimulation to suppress a nerve) applied to the *same* nerve would have different effects. Rather, Tanagho et al teaches positioning one set of electrodes in one location and a second set of electrodes in a different location to produce different effects. For instance, from column 2, lines 1-17:

In its broadest aspect, the system of this invention comprises an electronic control for sending electrical stimulation signals to first and second stimulation systems implanted in a body, the stimulation systems having electrodes positioned, respectively, on nerves controlling two different bodily functions, the electronic control system functioning to send stimulation signals normally to the first stimulation system. At a desired time, the electronic control will cease sending stimulation signals to the first stimulation system and, after a predetermined delay, will send stimulation signals to the second stimulation system. After a predetermined period, the electronic control will automatically cease sending stimulation signals to the second stimulation system and, after another predetermined delay, will resume sending stimulation signals to the first stimulation system.

This "micturition control system" is described in much more detail from column 9, line 37 through column 11, line 66, in connection with Figures 12-14. The continence control system is labeled with the symbol IS and evacuation with the symbol SR. Note column 9, lines 59-63:

The symbol SR as used herein depicts a component of the control system connected to an electrode implanted on a particular sacral nerve or root, whereas IS depicts connection to inferior somatic nerve S₁, controlling continence.

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Again, Tanagho only activates nerves with excitatory stimulation. For instance, at column 12, lines 15-18, Tanagho et al state (emphasis added):

This method of stimulation allows the muscles and nerves to recover between trains of stimuli while other nerves and muscles are being activated to continue the desired physiological effect.

Furthermore, at column 12, lines 46-50, Tanagho et al indicate (emphasis added):

Ideally, each electrode contact would function to activate the proper proportional number of fibers, e.g., in the case of two contacts, each contact would activate one-half of the fibers and in the case of four contacts, each contact would activate one-quarter of the fibers, etc.

While the present invention uses inhibitory stimulation to suppress nerve activity, Tanagho surgically separates (i.e., sections or isolates) nerve fibers to suppress activity of such nerve fibers. For instance, at column 4, lines 35-41, Tanagho et al state:

The ability of this invention to isolate various components of the various nerves... has enabled the applicants herein to isolate and selectively stimulate the particular nerve fibers that will effect the specific function or functions required.

As described earlier, applicant, in contrast, is claiming applying *inhibitory* stimulation to *parasympathetic nerves* to treat urgency, frequency, urinary incontinence, and/or fecal incontinence, and applying inhibitory stimulation pulses to *sympathetic nerves* to treat urinary and/or fecal retention. This inhibitory nerve stimulation is not taught or suggested by Tanagho, alone or in combination with Schulman (5193540), and therefore should be considered allowable.

Additionally, the prior art made of record in paragraph 6 of the Office Action does not teach or suggest the claimed invention. For instance, Vincent et al (3628538) use stimulation up to 1000 Hz, but this stimulation is applied to muscle tissue. The other prior art either does not teach nerve stimulation or applies excitatory stimulation (e.g., Sawan (6393323) applies stimulation at 15-40 Hz; Boveja (6205359) applies stimulation at 15, 20, 25, or 30 Hz; Lin (5833595) applies stimulation at 20 or 30 Hz; and Najafi et al (5314458) apply stimulation at up to 40 Hz). As such, applicants respectfully request reconsideration of original independent

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claims 1 and 31, consideration of amended independent claims 11, 20, and 32, and their dependent claims, in light of these remarks and the related claim amendments.

On page 4, in paragraph 5 of the Office Action, claims 7, 18, 25, 26, 28 and 29 were rejected under 35 U.S.C. 103(a) as unpatentable (obvious) over Tanagho et al in view of Schulman et al as applied to claim 1, and further in view of Lin (5833595). As claim 7 depends from claim 1, and claim 1 should be allowable for the foregoing reasons, claim 7 should also be allowable. As claim 18 depends from claim 11, and amended claim 11 should be allowable for the reasons given above, claim 18 should also be allowable. As claims 25, 26, 28 and 29 depend directly or indirectly from claim 20, and as claim 20 has been amended to incorporate the subject matter of dependent claim 23 and should be allowable for the foregoing reasons, claims 25, 26, 28 and 29 should also be allowable. Applicants respectfully request acknowledgement of the same.

In view of the foregoing, it is respectfully submitted that the rejections have been overcome and the pending claims are in condition for allowance. An indication of allowability of all pending claims, claims 1, 3-11, 14-21 and 25-32, at an early date is earnestly solicited.

Respectfully Submitted,

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Date

Laura A Bishop
Laura Haburay Bishop
Reg. No. 47,424

Please direct all written inquiries to:
Bryant R. Gold
Advanced Bionics Corporation
12740 San Fernando Road
Sylmar, CA 91342

Please direct all telephone inquiries to:
Laura Haburay Bishop
Telephone: (661) 362-1906
Fax: (661) 362-1507

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